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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,985	09/15/2005	Karl Lintner	SEDERM3.3-011	4999

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EXAMINER	
AULAKH, CHARANJIT	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/525,985	LINTNER, KARL	
	Examiner	Art Unit	
	Charanjit S. Aulakh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ~~5/26/2006~~ 02/25/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. According to a preliminary amendment filed on Feb. 25, 2005, the applicants have canceled claims 1-17 and furthermore, have added new claims 18-38.

2. Claims 18-38 are now pending in the application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no written description regarding various steps involved in either extracting the instant compounds of formula I from glaucium flavum or synthesizing them chemically except one compound in example 1 on page 20.

5. Claims 18 and 20-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following eight different factors (see Ex parte Foreman, 230 USPQ at

547; Wands, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on atleast four of the above mentioned eight different factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples, the state of the prior art, unpredictability and the breadth of claims.

The specification only teaches preparing one single compound in example 1 on page 20.There is no teaching or guidance present in the specification for preparing any other compound encompassed by compounds of instant formula I except one compound of claim 19. There is no teaching or guidance in the specification for preparing cosmetic or dermopharmaceutical compositions comprising instant compounds of formula I alone except compound of claim 19 and furthermore, there is no teaching for preparing these compositions comprising any other active substances or principal adjuvants. There are no working examples present for preparing such compositions comprising instant compounds of formula I in combination with any other active substances or principal adjuvants. There is no teaching in the specification or prior art that combination of structurally closely related compounds with any other active substance are well known to have pharmaceutical utility. There is lot of unpredictability regarding pharmaceutical utility of combination of instant compounds of formula I with any other active substance.

The instant compounds of formula I and active substances encompass several hundreds of thousands of compounds and therefore, in absence of such teachings, guidance and presence of working examples, it would require undue experimentation to demonstrate preparation and efficacy of instant compounds of formula I alone as well as combination with additional hundreds of thousands of active substances in known animal models of any disease condition and hence their pharmaceutical utility.

In regard to method claims 37 and 38, the specification is also not enabling. The specification teaches inhibitory effect of a single compound (compound of formula I where R2 and R3 variables represent a methyl group and variables R1 and R4 represent an acyl group) on G-3-PDH activity, peroxidation and melanogenesis in vitro (see examples 5-7 on pages 22-25). However, there is no teaching or guidance present how the instant compounds will decrease pigmentation (where melanin pigment is already formed), slim, reduce cellulite or firm the skin of a person. There are no working examples present showing efficacy of instant compounds in known animal models of these conditions. There is no teaching in the specification or prior art for well known utility of structurally closely related compounds in these conditions. The instant compounds of formula I and active substances encompass several hundreds of thousands of compounds and therefore, in absence of such teachings, guidance and presence of working examples, it would require undue experimentation to demonstrate the efficacy of instant compounds of formula I in combination with additional hundreds of thousands of active substances in known

animal models of dermatological conditions mentioned in instant claims 37 and 38 and hence their utility for treating such conditions

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 19-22, 26, 29-32, and 34-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 does not end with a period.

In claim 20, steps for extracting compounds of formula I from glaucium flavum are missing.

In claim 21, steps for preparing compounds of formula I are missing. It is not clear what are the reactants, starting materials etc.?

In claims 22, 37 and 38, the terms ---active substance or principal adjuvant --- is indefinite since specific substance or adjuvant is not defined.

In claim 26, the term ---other inorganic support --- is indefinite since it is not defined.

In claims 29 and 30, specific substances, actives and agents are not defined.

In claims 31, 32 and 34-36, specific plant extract is not defined.

Claim Rejections - 35 USC § 102

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 18 and 21-36 are rejected under 35 U.S.C. 102(a) as being anticipated by Su (U.S. Patent 6,313,134).

Su discloses uses of Thaliporphine derivatives, pharmaceutical compositions containing these compounds for the treatment of cardiac diseases. The compounds of formula I (see col. 2, lines 25-46) as well as formula II (see col. 3, lines 1-22) disclosed by Su anticipate the instant claims when R1, R3 and R4 represent methyl group and R2 represents hydrogen or acetyl group in the instant compounds of formula I.

9. Claims 22-38 rejected under 35 U.S.C. 102(a) as being anticipated by lintner (WO 02/066000).

Lintner discloses novel cosmetic compositions containing Boldine for treating excess weight, cellulite and skin toning. The cosmetic composition comprising Boldine (see examples 1-3 on pages 4-5) disclosed by Lintner anticipates the instant claims when R1 and R4 represent –OH while R2, R3 and R5 all represent methyl group in the instant compounds of formula I.

10. Claims 22-36 are rejected under 35 U.S.C. 102(a) as being anticipated by Pauly (EP 1145709).

Pauly discloses natural products for cosmetic compositions. The cosmetic composition comprising Boldine anticipates the instant claims when R1 and R4 represent –OH while R2, R3 and R5 all represent methyl group in the instant compounds of formula I.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 18 and 21-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Krell (WO 99/16441).

Krell discloses Aporphinoid compounds, pharmaceutical compositions containing these compounds for treating MMP-mediated diseases. The compounds, boldine and glaucine

(see compounds 7 and 12 on page 10) as well compounds 30-40 (see examples 30-40 in columns 13-14) disclosed by Krell anticipate the instant claims when R1-R4 represent H or alkyl groups and R5 represents a methyl group in the instant compounds of formula I.

12. Claims 22-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Nizard (WO 00/59466).

Nizard discloses cosmetic compositions. The cosmetic composition comprising Boldine (see example VIII on page 24) disclosed by Nizard anticipates the instant claims when R1 and R4 represent –OH while R2, R3 and R5 all represent methyl group in the instant compounds of formula I.

13. Claims 18, 22 and 24-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Maasbol (U.S. Patent 4,279,914).

Maasbol discloses Thrombocyte aggregation inhibiting compositions and methods. The compound disclosed in example 3 (see col. 2, lines 40-54) disclosed by Maasbol anticipates the instant claims when R1-R4 all represent H in the instant compounds of formula I.

14. Claims 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Cortes (J. of natural products).

Cortes discloses noraporphine compounds. The compounds 6 and 8 (see page 865) disclosed by Cortes anticipate the instant claims when R5 represents H or methyl group, R1 and R4 represent acyl group or –OH group and both R2 and R3 represent methyl group in the instant compounds of formula I.

15. Claims 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoshino (Chem. Pharm. Bull.).

Hoshino discloses studies on tetrahydroisoquinolines. The compounds 3a, 3c, 4a and 4d (see page 3103) disclosed by Hoshino anticipate the instant claims when R5 represents methyl group in the instant compounds of formula I.

16. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Chen (Planta Medica).

.Chen discloses Antiplatelet and vasorelaxing actions of some aporphinoids. The compounds 8 and 10-12 (see fig. 1 on page 134) anticipate the instant claim when R5 represents H, methyl or an acyl group in the instant compounds of formula I.

17. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Yu (Biochem. Journal).

Yu discloses inhibition of nitric oxide synthase by Thaliporphine. The compound, Thaliporphine (see fig. 1) disclosed by Vu anticipates the instant claim when R2 represents h and r1, R3, r4 and R5 all represent methyl group in the instant compounds of formula I.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1625